IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: ETHICON WAVE 5 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS OF RAGNVALD MJANGER, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this response in opposition to Plaintiff's Motion to Exclude Certain Opinions of Ragnvald Mjanger, M.D. *See* Doc. 4414 and 4415.

INTRODUCTION

Dr. Mjanger is an obstetrician and gynecologist focusing on treating incontinence, prolapse and other pelvic floor disorders. Doc 4414-3, Ex. C. to Pls.' Motion, Expert Report at 1. He has been board-certified in obstetrics and gynecology since 2000 and Female Pelvic Medicine and Reconstructive Surgery since 2015. *Id.* at 1 and Doc 4414-2, Ex. B to Pls.' Motion, Mjanger CV at 1. Dr. Mjanger is a clinician, in private practice in St. Paul, Minnesota and an Assistant Clinical Professor at the University of Minnesota Medical School. *Id.*

Dr. Mjanger has performed over 10,000 pelvic surgeries including many different types of procedures to treat stress incontinence, including open and laparoscopic retropubic urethropexies, Burch and Marshall-Marchetti-Krantz (MMK) procedures, needle suspensions, fascial bladder neck slings, and synthetic mid-urethral slings. Doc. 4414-3, Pls. Motion, Ex. C, Expert Report at 1. He has also taught other physicians how to perform these procedures. *Id.*

Dr. Mjanger also performs revision procedures. Doc. 4414-4, Pls.' Motion, Ex. D, 7/20/17 Mjanger Dep. at 60:11-21.

In these cases, Dr. Mjanger intends to offer opinions generally addressing the utility and safety of the TVT and TVT-O devices. His opinions are based upon his education, medical training, clinical experience, review of medical literature, position statements, guidelines, curricula, and various other materials reflected in his reliance list. Doc. 4414-3, Pls.' Motion. Ex. C, Expert Report at 1-2; Ex. A hereto, Reliance List. Although Plaintiffs have challenged certain aspects of Dr. Mjanger's opinions, as set forth below, he is qualified to opine on these topics and his opinions are supported by a reliable methodology. Plaintiffs' arguments lack merit and should be denied.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

I. Dr. Mjanger is qualified to testify regarding the adequacy of the warnings.

Dr. Mjanger has opined on the adequacy of the TVT and TVT-O IFU warnings from a clinical perspective based on his knowledge of and clinical experience with the devices. *E.g.*, Doc. 4414-3, Pls.' Motion. Ex. C, Expert Report at 2, 12-13. Plaintiffs do not challenge, or even address, Dr. Mjanger's clinical expertise. Instead Plaintiffs argue that he is not qualified to opine on the adequacy of the IFUs because he lacks familiarity with the regulatory process governing the development of such documents.

Ethicon concedes that Dr. Mjanger is not a regulatory expert and will not opine on warnings from that perspective. Consistent with the Court's prior rulings as to other urogynecologist expert witnesses [Dr. Flynn], however, Dr. Mjanger, as an Ob/Gyn and female pelvic medicine and reconstructive specialist, "he may testify about the specific risks of

implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon*, 2016 WL 4582231, at *3 (S.D. W. Va. Aug 31, 2016). Dr. Mjanger's report details his experience with the TVT and TVT-O devices, including particular risks and complications he has experienced. Doc. 4414-3, Pls.' Motion. Ex. C, Expert Report at 12-13. His extensive clinical experience with the products at issue is supplemented by a thorough review of the relevant literature, his education and training, including education he has provided to others. *Id.*, Ex. A hereto, Reliance List; Doc. 4414-2, Pls.' Motion Ex. B, Mjanger CV.

Plaintiffs do not appear to challenge Dr. Mjanger's competency to testify that risks that did not appear on the IFUs were already commonly known to clinicians but to the extent that their motion is construed to do so, any such challenge should be denied. Dr. Mjanger will testify that the complications that Plaintiffs allege should have been in the IFUs: (a) are risks that a pelvic surgeon would already know, and therefore, need not be warned about; (b) are not genuine complications; or (c) are not attributable to the device. Doc. 4414-4, Pls.' Motion Ex. D, 7/20/17 Mjanger Dep. at 283-285, 288.

As it relates to the latter two categories, Dr. Mjanger's report shows that his opinions are based on his extensive clinical experience, *as well as* his critique of scientific literature. *See, e.g.*, Doc. 4414-3, Pls.' Motion. Ex. C, Expert Report at 8-10. (explaining why he disputes that mesh causes various conditions, such as damage from contraction, cytotoxicity, or degradation); s*ee also Huskey*, 29 F. Supp. 3d at 734-35 (allowing Dr. Johnson to testify about evidence of

absence because his opinions were also based on medical literature); *Carlson*, 2015 WL 1931311 at *12 (S.D. W. Va. Apr. 28, 2015).[1]

Dr. Mjanger, as an experienced clinician, is well qualified to testify about complications that are commonly known such that they need not be included in an IFU. Doc. 4414-3, Pls.' Motion. Ex. C, Expert Report at 12-13. The law imposes no duty to warn sophisticated users of products with respect to risks that the sophisticated users already know or should know. *See, e.g.*, Restatement (Third) Tort: Product Liability §2 cmt. J. (1988); Restatement (Second) of Law of Torts §402A cmt. J.; American Law of Product Liability 3d § 32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990). In fact, 21 CFR §801.109(c) states there is no duty to warn if "the article is a device for which the hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Experts may testify as to the knowledge common within a profession or community. *See Flannery v. Bauermeister*, No. CIV. A. 06-399S, 2008 WL 77723, at *2 (D. R.I. Jan. 4, 2008) (granting summary judgment in part based on testimony from defendants' experts as to what "is known within the correctional medical community")' *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (allowing expert testimony of "common knowledge")'; *U.S. v. Articles of Device*, 426 F.

[1] While this Court has observed that '[a]bsence of evidence is not evidence of absence," *Tyree*, 54 F. Supp. 3d 501, 583-84 (S.D. W. Va. 2014), the observation only holds true where a cursory inquiry of the evidence has been made. For instance, if a physician is relying merely on his own experience to opine that a particular risk does not exist, the methodology may be flawed. However, where, as here, a physician examines the evidence outside of his own experience, such as by critiquing the medical literature and studying the conclusions of medical organizations, then the physician's opinions have a reliable basis. If there is no reliable evidence of risk as determined by a detailed review of appropriate sources, there is no obligation to include the risk in the IFU warnings.

Supp. 366 (W.D. Pa. 1977) (FDA offered affidavit in misbranding case). Thus, the TVT and TVT-O IFUs supplement all of the other sources of a surgeon's knowledge.

This is an objective test not dependent on the knowledge of the individual surgeon, and Dr. Mjanger is certainly competent to share his opinions about what risks should be obvious to surgeons who use the devices and how an average clinician would construe the IFUs. Indeed, Ethicon writes its IFUs for pelvic floor surgeons like Dr. Mjanger. Under the learned intermediary doctrine, such surgeons are the ones who must be adequately warned. If Plaintiffs intend to argue at trial that Ethicon's IFU failed to disclose certain risks, then it is only fair that Ethicon be allowed to defend itself by demonstrating that those risks were obvious to the users of the product (pelvic surgeons), and therefore, did not need to be included in the IFUs in accordance with the aforementioned law.

II. Dr. Mjanger is qualified to render opinions regarding the utility and safety of the TVT and TVT-O devices, and his opinions are supported by reliable methodology

Plaintiffs claim that Dr. Mjanger "should be precluded from giving design opinions" on the basis that he has inadequate expertise with the design process and product development. Doc. 4415, Pls.' Motion at 7. As set forth below, Dr. Mjanger does not intend to provide design process opinions, and he is well qualified to testify about the safety and utility of the devices.

A. Dr. Mjanger will not provide design process opinions

Plaintiffs made this same challenge as part of their motions to exclude other defense expert opinions in Wave 1 cases. Noting that Plaintiffs' motion was "plagued with confusion about what constitutes a design opinion," the Court correctly found that "[Dr. Woods] has not expressed any opinions about the process of designing a product." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582231, at *3 (S.D. W. Va. Sept. 1, 2016). Therefore, the Court denied Plaintiffs' challenge to the defense experts design opinions "as moot". *Id.*

The Court should make the same finding in this Wave of cases. Dr. Mjanger does not intend to opine about product design and development, and Plaintiff's motion should not be construed as challenging Dr. Mjanger's opinions about the safety and efficacy of TVT or TVT-O.

B. Ethicon's internal product design process documents are irrelevant to Dr. Mjanger's safety and utility opinions.

Relying exclusively on this Court's opinion in *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222 (S.D. W. Va. Apr. 24, 2015), Plaintiffs argue that because Dr. Mjanger has not reviewed Ethicon's internal documents about its design process, he cannot opine about any issues that touch upon product design. As previously noted by Ethicon, Dr. Mjanger does not intend to offer *any* opinion regarding the adequacy of Ethicon's internal design procedures or Ethicon's compliance with industry standards during the development of the devices. To the extent that Plaintiffs seek to use Dr. Mjanger's failure to review certain design process documents as a basis to exclude his opinions about the safety and efficacy of TVT and/or TVT-O, Plaintiffs' motion lacks merit and should be denied.

This Court's decision in *Winebarger* lends no support to Plaintiffs' argument. In that case, Boston Scientific challenged the opinion of the plaintiff's proposed expert, Dr. Bobby Shull, regarding Boston Scientific's failure to "follow its own internal protocols" and its "lack of due diligence in the design and development" of the product in issue. *Winebarger*, at *14. Dr. Shull, however, did not review any documents related to Boston Scientific's standard operating procedures or its design protocols. *Id*. Consequently, this Court held that "[w]ithout any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures for the norm; (2) not followed by BSC; or (3) lacking in any way." *Id.*

In contrast to Dr. Shull in *Winebarger*, Dr. Mjanger does not intend to offer any opinions regarding Ethicon's "internal design procedures," and therefore, it was unnecessary for Dr. Mjanger to review any of Ethicon's internal documents related to design procedures. In fact, in *Winebarger*, the Court allowed Dr. Patrick Culligan, a defense expert urogynecologist, to opine about the safety and efficacy of the medical device, even though the Court concluded that Dr. Culligan was not competent to testify about mesh design. *Id*. at *33-35. This Court has found that other physicians with surgical experience were competent to offer opinions similar to that of Dr. Mjanger. *See, e.g., Tyree*, 54 F. Supp. 3d at 550; *Jones v. Bard, Inc.*, No. 2:11-cv-00114 [Doc. 291], pp. 6-9; *Trevino v. Boston Scientific Corp*., 2016 WL 1718836, at *33 (S.D. W. Va. Apr. 28, 2016).

Plaintiffs have chosen to focus on an opinion Dr. Mjanger has not offered related to documents Dr. Mjanger was not even asked to review. Quite simply, Plaintiffs have not shown and cannot show that a review of Ethicon's internal product design process documents was necessary for any of the opinions that Dr. Mjanger intends to provide in these cases.

C. The complication and satisfaction rates in Dr. Mjanger's practice are consistent with the rates reported in the peer-reviewed medical literature.

Plaintiffs argue that Dr. Mjanger should be precluded from opining on the design of the TVT and TVT-O "being reasonably safe" because he relies "solely on his personal experience using the products and not the design protocols or methodology of a medical device manufacturer." Doc. 4415, Pls. Motion at 9-10. Ethicon acknowledges that, in its Wave 1 rulings, the Court excluded expert witness opinions regarding complication rates in an expert's own practice on the basis that "his complication rates derive entirely from mental estimates and not from accumulated data or patient records." *In re: Ethicon,* 2016 WL 4582231, at *3. Ethicon respectfully suggests that Dr. Mjanger's opinions about these rates in his own practice

are sufficiently reliable and that the Court allow Dr. Mjanger to testify about such rates consistent with other decisions issued by the Court. *See Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Doc. 265, p. 40 (S. D. W. Va. Nov. 20, 2014) ("If *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions"); *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222, at *34 (S.D. W. Va. Apr. 24, 2015) (finding that expert's inability to provide "exact statistics" about the outcome of his patients did not render his personal experience opinions unreliable and that "such detail is not required under *Daubert* to opine as to '*large-scale'* safety and efficacy of the Uphold device"); *Trevino v. Boston Scientific Corp*., 2016 WL 1718836, at *33 (S.D. W. Va. Apr. 28, 2016) (same).

Alternatively, the Court, as it did in its Wave 1 rulings, should limit its exclusion of Dr. Mjanger's opinions to his statements about his own patient's outcomes. To the extent that Plaintiff's motion could be construed as challenging Dr. Mjanger's ability to provide opinions about the safety and efficacy of TVT and TVT-O beyond his own personal experience, it should be denied.

Indeed, Dr. Mjanger's extensive personal experience, coupled with his reliance on medical literature, make him well-qualified to opine about the safety and utility of the devices. Dr. Mjanger is a skilled female pelvic floor surgeon with over 25 years of experience treating stress urinary incontinence and female pelvic floor disorders, as well as the complications resulting from the implantation of transvaginal mesh. Doc. 4414-3, Pls.' Motion. Ex. C, Expert Report at 1. He has implanted thousands of TVT and TVT-O devices and regularly treats patients for complications related to pelvic surgery. *Id.*; Doc. 4414-2, Pls.' Motion Ex. B, Mjanger CV.

As reflected in his report, and supported by published studies, the rate of mesh exposure for TVT ranges on average from 1- 3% in the peer reviewed literature. E Doc. 4414-3, Pls.' Motion. Ex. C, Expert Report at 6-8; Doc. 4414-4, Pls.' Motion Ex. D, 7/20/17 Mjanger Dep. at 279-282. Dr. Mjanger believes his personal success and complication rates to be generally consistent with the peer-reviewed scientific literature. Doc. 4414-4, Pls. Motion Ex. D, 7/20/17 Mjanger Dep. at 279-282.

III. Dr. Mjanger is competent to testify about degradation.

As this Court concluded in its rulings in Wave 1 as to Plaintiff's argument that another expert witness [Dr. Flynn] was not competent to testify about degradation was "without merit." *In re: Ethicon,* 2016 WL 4556807, at *4 (S.D. W. Va. Aug. 31, 2016). The Court held that Dr. Flynn's "extensive clinical experience, combined with [his] review of the scientific literature, qualifies [him] to opine on mesh's reaction to and effect on the human body." *Id*. The same analysis should apply to Dr. Mjanger.

Dr. Mjanger's opinions are particularly bolstered by his review of Level 1 long-term studies, RCTs, systematic reviews, meta-analyses, and Cochrane reviews demonstrating the safety of polypropylene mesh and that the mesh is not degrading. *See, e.g.*, E Doc. 4414-3, Pls.' Motion. Ex. C, Expert Report at 6-10; Doc. 4414-4, Pl's Motion Ex. D, 7/20/17 Mjanger Dep. at 289-290. As stated in Dr. Mjanger's report, "Clinical evidence, including my own clinical experience, established that TVT mesh does not degrade in vivo. If it does, any such degradation does not (find any possible testimony that would work here about his personal experience and any literature testimony). Doc. 4414-3, Pls.' Motion. Ex. C, Expert Report at 9.

Plaintiffs fault Dr. Mjanger for not reviewing the devices' design history files, but Dr. Mjanger does not offer opinions about Ethicon's process of developing products. Indeed,

Dr. Mjanger's opinions about degradation are not at the molecular level and the equivalent of the opinions of a polymer scientist, but instead, are focused on clinical aspects of alleged degradation. *See Wilkerson*, 2015 WL 2087048, at *20 (S.D. W. Va. May 5, 2015). ("That he [Dr. Porter] has no experience in polymer science is irrelevant because Dr. Porter is not offering opinions about 'what's happening at the molecular level'").

Plaintiffs also argue that Dr. Mjanger should not be allowed to testify about the lack of any meaningful clinical effects of degradation, because he "does not hold himself out as an expert in chemical engineering, pathology, or polymer chemistry."; "has not done any bench or lab research on polypropylene or polypropylene meshes"; "has never performed any kind of pathological analysis on any explanted polypropylene meshes and . . . is not a biomaterials specialist." Pl's Motion at 11. In *Huskey*, this Court rejected a similar challenge to defense expert urogynecologist, Harry Johnson, M.D. 29 F. Supp. 3d at 735. Noting that although "Dr. Johnson's opinion is not subject to testing and it is not supported by peer-reviewed literature *affirmatively* stating that degradation lacks clinical significance," Dr. Johnson's "clinical experience and his review of the scientific literature" set forth a sufficient basis for his opinion and "Dr. Johnson's failure to review particular documents goes to the weight of his opinion, not its admissibility." *Id.* Again, "[i]f there are certain device-specific publications that [Plaintiffs claim that Dr. Flynn] failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination." *Trevino*, 2016 WL 2939521, at *41.

IV. Dr. Mjanger's opinions regarding safety and efficacy of the TVT and TVT-O are based in sound methodology.

Dr. Mjanger has applied a sound methodology in formulating his opinions regarding the safety and efficacy of TVT and TVT-O and the rates referenced in his testimony are supported by his thorough review of peer-reviewed publications demonstrating the long-term safety of the

devices, as well as the repeated endorsement of medical societies. Doc. 4414-4, Pls.' Motion Ex. D, 7/20/17 Mjanger Dep. at 279-282. His opinions are also supported by his decades of clinical experience and medical training. Although Dr. Mjanger could not verify precise percentages for specific types of complications realized in his practice, that failure does not impact his ability to testify about the safety and efficacy of TVT and TVT-O, as demonstrated by the scientific literature that he has reviewed.

This Court has recognized that a physician may testify that complication rates found in literature are verified by his personal experience. *See, e.g., Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014) (expert applied reliable methodology supporting opinion that product was safe and effective where opinion was based upon "minimal complications in his clinical practice" which was "on par with the findings of [the] studies' he cites throughout his expert report"); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *12, *36 (S.D. W. Va. Apr. 28, 2015) (finding Dr. Galloway's method of considering scientific articles and drawing on his clinical experience to reach his opinion regarding degradation to be methodologically sound and allowing Dr. Culligan "by way of his experience with the Uphold device and his review of the relevant scientific literature" to opine how these procedures compare.) That is precisely what Dr. Mjanger will do in these cases. Any alleged inconsistencies or weaknesses in Dr. Mjanger's testimony go to its weight, not its admissibility. *See Daubert*, 509 U.S. 579, 596 (1993) ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attaching shaky but admissible evidence.")

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court deny Plaintiffs' motion to exclude Dr. Mjanger's testimony.

Dated: August 29, 2017.

Respectfully submitted,

NILAN JOHNSON LEWIS PA

By: */s/ Tracy J. Van Steenburgh*
Tracy J. Van Steenburgh
Reg. No. 141173
Nilan Johnson Lewis PA
120 South Sixth Street, Suite 400
Minneapolis, MN 55402-4501
Telephone: (612) 305-7500
Facsimile: (612) 305-7501
tvan@nilanjohnson.com

Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com

David B. Thomas (W.Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
dthomas@tcspllc.com

COUNSEL FOR DEFENDANTS
ETHICON, INC. AND JOHNSON & JOHNSON

CERTIFICATE OF SERVICE

I hereby certify that on August 29, 2017 I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ Tracy J. Van Steenburgh
Tracy J. Van Steenburgh